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March 2, 2015

U.S. ex rel. Kester v. Novartis Pharmaceuticals Corp.
No. 11 Civ. 8196 (CM) (JCF)

Dear Judge Francis:

We represent Defendant Novartis Pharmaceuticals Corporation ("Novartis" or the "Company") in the above-referenced matter. We write in response to the letter that the United States and the intervening states (collectively, the "Government") submitted to the Court on February 27, 2015 (the "Gov't Letter"). (ECF No. 351.) For the reasons set forth below, we respectfully request that the Court deny the relief sought.

As a threshold matter, we believe it is important to explain what Novartis is facing with respect to ongoing discovery demands. Among other things, those demands impede the Company's ability to provide the waiver documents any more quickly than the schedule it already has proposed.

During its two-year pre-suit investigation, the Government demanded that Novartis collect, review and produce over 15 million pages of material. The Government also took testimony from numerous witnesses, including 19 former and current Novartis employees, as well as various third parties from the pharmacies at issue. In fact, at the initial conference on March 14, 2014, Judge McMahon stated that, having "investigat[ed] with subpoena power and all the powers the government has, for two and a half years", the Government should not "have to find out anything" else, (Conf. Tr. 53:23-54:1, Mar. 14, 2014, ECF No. 159) and "[a]s far as I'm concerned, you know what you've got to know" (Conf. Tr. 53:3-4).

Nevertheless, since March 2014, the Government has propounded 43 additional requests for production of Exjade documents, and the Relator has propounded 82 additional requests for production, including one Exjade-related request propounded as recently as February 17. In response to these requests (and other post-investigation requests), Novartis has made an additional 55 productions since March 2014, totaling more than 40 million pages, bringing the document production in this case to date to more than 55 million pages. We submit that the discovery demands to which Novartis has been subjected go far beyond the scope of

discovery anticipated by the Federal Rules of Civil Procedure, and what Judge McMahon appeared to envision at the March 14 conference. It is these continuing requests for production that have made it challenging for the parties to meet the discovery schedule set by Judge McMahon, not Novartis's decision to waive privilege.[1]

Turning now to the Government's arguments specifically related to Novartis's privilege waiver:

First, we disagree with the Government's suggestion (Gov't Letter at 1) that Novartis was dilatory in asserting its intent defense. It is true that when the Government first asked in June and July 2014 whether Novartis planned to rely upon "advice of counsel", the Company's lawyers responded that "NPC does not currently intend to assert an advice of counsel defense". However, counsel made clear that if the Company's "view on that issue changes, we will advise you in sufficient time for the United States to take necessary discovery regarding that defense". (Gov't Letter, Ex. A at 1-2, ECF No. 351-1.)

Since July, there have been significant developments that Novartis took into account in reconsidering its waiver decision. On August 7 and September 4, 2014, Judge McMahon denied Novartis's motions to dismiss the Government's complaints, rejecting Novartis's argument that the Government was required (and failed) to plead that the alleged kickback schemes "caused" doctors to prescribe Myfortic and patients to order refills of Exjade.[2] In addition, as a result of this Court's November 24 decision on Novartis's motion to compel production of documents related to the Government's own adherence programs, Novartis did not receive evidence upon which it had intended to rely to demonstrate the Company's good faith in designing and operating similar programs without having to waive privilege. (See Mem. & Order at 12, Nov. 24, 2014, ECF No. 307 (NPC wanted to use the evidence to "undermine the argument that Novartis' conduct was 'willful' as required by the Anti-Kickback Statute".); Conf. Tr. 21:3-21, Mar. 14, 2014, ECF No. 159 (NPC explained that "there will be . . . a ton of evidence to show that the government itself proclaims the virtues of adherence programs . . . .").)

Novartis therefore revisited the waiver question and ultimately determined that evidence reflecting legal advice in connection with the Exjade adherence activities challenged by the Government was key to demonstrating the Company's good faith and intent. But the decision to waive privilege is a difficult one, and Novartis understandably needed to consider that decision carefully and at various levels of the organization, while at the same time continuing to respond to the multiple document requests and deposition notices it was receiving. The Company did not finally reach a decision until February 16, 2015, and it notified the Government of its decision the very next day. (See Ex. A at 8.) Indeed, in an effort to inform

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[1] In addition to the ongoing production requests, the Company has also been faced with the Relator's demands for production of additional privilege logs on an accelerated schedule (currently the subject of a pending motion to compel) and documents related to three drugs (Tobi, Tasigna and Gleevec) that are on a more elongated schedule and rightfully should be placed after Exjade and Myfortic in terms of priority.

[2] The Government's present submission relates only to Exjade.

the Government of the decision sooner rather than later, Novartis communicated its decision to the Government prior to completing the collection and review of all relevant documents. As a result, Novartis is still in the process of collecting, reviewing and producing documents subject to the waiver as expeditiously as possible (discussed further below).

Second, the Government asks the Court to direct Novartis to "take steps to ensure that its production of the 'waiver' documents contain all documents relevant to legal advice that bears on any aspect of Novartis's relationship with the three Exjade pharmacies, regardless of whether it specifically references Exjade or adherence". (Gov't Letter at 2.) We are frankly not sure what the Government means by this statement. If it is asking for all documents relevant to legal advice concerning the Exjade activities challenged by the Government and the Relator, we intend to produce that material.

In various email exchanges, Novartis has fully set forth the scope of its waiver and the resulting document collection and production. (See Ex. A at 4, 6, 8.) Of relevance here, Novartis has stated explicitly that it does not intend to limit its production of privileged documents to those that "specifically reference Exjade or adherence" (Ex. A at 4, 6), and has already produced examples of such documents (see, e.g., Ex. B (produced February 27, 2015)). Novartis also has confirmed that it is collecting and producing all documents relevant to legal advice concerning the challenged Exjade-related activities, including any documents provided to counsel in connection with such advice and any responsive drafts, attorney notes and attorney-to-attorney communications. (See Ex. A at 4.) These representations adequately address the concerns raised by the Government in its letter.

To the extent the Government seeks to expand the waiver beyond the challenged conduct to encompass "any aspect of Novartis's relationship with the three Exjade pharmacies", that request should be denied. As a participant in a highly regulated industry such as the pharmaceutical industry, Novartis seeks legal advice on numerous issues, many of which have no relevance to the claims asserted by the Government and the Relator. The Government itself argued before this Court in opposition to Novartis's motion to compel adherence materials that discovery "does not encompass 'requests based on pure speculation that amount to nothing more than a "fishing expedition" into actions . . . not related to the alleged claims or defenses'". (Pl.'s Mem. Opp. to Def.'s Mot. to Compel, at 10, Sept. 29, 2014, ECF No. 280 (quoting Collens v. City of New York, 222 F.R.D. 249, 253 (S.D.N.Y. 2004).) Again, the Government has alleged particular violations of the Anti-Kickback Statute and False Claims Act. Novartis has waived the privilege with respect to those allegations concerning Exjade.

Third, the Government's request that this Court compel the Company to finish production of all waiver documents by March 4 imposes an unfair burden, particularly in light of all the other pending document requests and production the Company is trying to address. Novartis simply cannot produce all the documents over which Novartis intends to waive attorney-client privilege by March 4. Since the decision was reached, Novartis has been diligently reviewing for waiver the privileged documents that had already been collected, and collecting new documents from additional custodians. While Novartis does not anticipate the volume of the soon-to-be-produced documents to be significant, the volume of privileged documents that must be reviewed for potential waiver is substantial and the review process is time-consuming.

On February 27, Novartis produced 137 documents subject to the waiver. Novartis's goal is to complete a rolling production of all waiver documents by mid-March.

Fourth, Novartis promptly informed the Government of the identity of the additional witnesses—attorneys (both internal and outside counsel) who provided legal advice with respect to the challenged Exjade-related activities. (See Ex. A at 2, 6.) We now understand that the Government also seeks from Novartis identification of which existing witnesses or custodians requested, received, provided and implemented the legal advice that is the subject of the waiver. Because Novartis informed the Government of its decision as soon as it was made, we are still in the process of identifying relevant witnesses. That said, the current custodians whose files will be searched in connection with the waiver are Emily Chee, William Hinshaw, Michael Mignogna, Peter Ng, Kenneth Olsen, Frank Padron and Paul Pochtar. To the extent Novartis learns that any other witness requested, received or implemented legal advice that is the subject of the waiver, we will immediately notify the Government and review his/her files for relevant documents.

Although Novartis appreciates the Government's desire to complete document production before commencing depositions, that has never been feasible—even prior to the privilege waiver—as all parties acknowledged from the outset. Novartis has made clear to the Government that it is eager to work with them to schedule the remaining depositions in a manner that will enable the parties to comply with the April 17 fact discovery deadline. (See Ex. A at 2, 6.) If necessary, Novartis is willing to proceed with depositions and to allow the Government to recall witnesses with respect to questions that relate to subsequently produced waiver documents.

Respectfully,

Evan R. Chesler /DH

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VIA ECF

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